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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
HUSON, MONICA ANNE	
ART UNIT	PAPER NUMBER
1791	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,651	ZHOU, PU	
	Examiner	Art Unit	
	MONICA A. HUSON	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,14 and 35-41* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13 and 35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the RCE filed 20 October 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 11, 13, and 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noone et al. (U.S. Patent 6,591,472), in view of Benjamin (U.S. Patent 6,245,053).

Regarding Claim 1, Noone et al., hereafter "Noone," show that it is known to carry out a method of forming a catheter (Abstract) comprising providing a braid layer having a distal end and a proximal end, an inner lubricious liner positioned within the braid layer (Column 8, lines 33-34, 49-50); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end (Column 9, lines 16-17); cutting through the braid layer and the inner lubricious liner at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position (Figures 5-6); and subsequent to cutting through the braid layer and the inner lubricious layer, securing a second polymer over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61). Noone does not show the second polymer segment extending distally and proximally of the cutting

position. Benjamin shows that it is known to carry out a method wherein a second polymer segment is placed over a first polymer segment and a braid layer, wherein the second polymer segment extends distally and proximally of the cutting position (Figures 6-7; second polymer segment=130; Column 9, lines 28-53). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Benjamin's second polymer segment over Noone's braided layer and first polymer segment in order to apply the desired compression to the first polymer segment and braided layer while bonding together.

Regarding Claim 11, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first polymer segment, and a distal segment configured to form a distal tip (Figure 8, element 75, 145), meeting applicant's claim.

Regarding Claim 13, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein providing the braid layer comprises providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (Figure 5, element 70), meeting applicant's claim.

Regarding Claim 35, Noone shows that it is known to carry out a method of forming a catheter (Abstract), comprising cutting a catheter subassembly at a cutting location (Figure 5, location 125), the subassembly having proximal and distal ends, an inner layer (Figure 5, element 65), a reinforcement layer on the inner layer (Figure 5, element 70), and a securement layer disposed over at least a portion of the reinforcement layer (Figure 5, element 100); removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location (Figure 6); and subsequent to removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location, securing a polymeric outer segment over at least the securement layer such that a portion of the polymeric outer segment extends distally of the cutting location (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12,

lines 9-11, 35-37, 52-61). Noone does not show the curve of the second polymer segment. Benjamin shows that it is known to carry out a method wherein a second polymer segment is secured over a first polymer segment and a braided layer, wherein the second polymer segment has a curved portion (Figure 7). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Benjamin's second polymer segment over Noone's braided layer and first polymer segment in order to apply the desired compression to the first polymer segment and braided layer while bonding together.

Regarding Claim 36, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method further comprising forming a portion of the polymeric outer segment into a distal tip for the catheter (Figure 8, element 25), meeting applicant's claim.

Regarding Claim 37, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method further comprising assembling the catheter subassembly by providing an inner subassembly having the reinforcement layer disposed on the inner layer (Figure 5, elements 65, 70); and disposing the securement layer on the inner subassembly by securing a securement segment thereon (Figure 5, element 100), meeting applicant's claim.

Regarding Claim 38, Noone shows the process as claimed as discussed in the rejection of Claim 37 above, including a method wherein the reinforcement layer has a distal end, the securement layer has a distal end, and the step of disposing the securement layer on the inner subassembly is performed such that the distal end of the reinforcement layer extends distally beyond the distal end of the securement segment (Figure 5,elements 70, 100), meeting applicant's claim.

Regarding Claim 39, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method wherein the reinforcement layer comprises a braided member (Column 8, lines 49-51), meeting applicant's claim.

Regarding Claim 40, Noone shows that it is known to carry out a method of forming a catheter (Abstract) comprising providing a braid layer having a distal end and a proximal end (Column 8, lines 33-34, 49-50); positioning an inner lubricious liner

within the braid layer (Column 8, lines 33-34, 49-50); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer (Column 9, lines 16-17); cutting through the braid layer and the inner lubricious liner at a cutting location proximal of the distal end of the braid layer, thereby forming a catheter subassembly including the inner lubricious liner, the braid layer, and the first polymer segment, the catheter subassembly having a distal end defined at the cutting location (Figures 5-6); and securing a second polymer over the catheter subassembly, the second polymer segment extending over the first polymer segment of the catheter assembly and extending distally of the distal end of the catheter subasembly (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61), wherein the step of securing the second polymer segment over the catheter subassembly is performed subsequent to the step of cutting through the braid layer (Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61). Noone does not show the second polymer segment extending distally and proximally of the cutting position. Benjamin shows that it is known to carry out a method wherein a second polymer segment is placed over a first polymer segment and a braid layer, wherein the second polymer segment extends distally and proximally of the cutting position (Figures 6-7; second polymer segment=130; Column 9, lines 28-53). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Benjamin's second polymer segment over Noone's braided layer and first polymer segment in order to apply the desired compression to the first polymer segment and braided layer while bonding together.

Regarding Claim 41, Noone shows the process as claimed as discussed in the rejection of Claim 40 above, including a method wherein providing the braid layer comprises providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (Figure 5, element 70), meeting applicant's claim.

Claims 2-5, 7, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noone and Benjamin, in view of Wilson (U.S. Patent 5,951,929).

Regarding Claim 2, Noone teaches the invention of claim 1 as discussed above, but does not expressly teach that the first polymer segment has a melting point that is at least about 10°F above a melting point of the second polymer segment. Wilson teaches using a blend of PEBA and approximately 30% $BASO_4$ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). Thus, Wilson teaches that the first polymer segment has a melting point that is at least 10°F (25°F) above the melting point of the second polymer segment. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's materials during Noone's method in order that the first polymer segment will not remelt upon application of the second polymer segment (Wilson, column 9, lines 41-50).

Regarding Claim 3, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the first polymer segment comprises positioning a heat shrink tube over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment (Column 7, lines 57-67; Column 8, lines 1-5). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's heat shrink tube during Noone's method in order to most efficiently bond the materials together.

Regarding Claim 4, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the second polymer segment comprises positioning a heat shrink tube over the second polymer segment and applying sufficient heat and pressure to melt the second polymer but not enough heat to melt the first polymer segment (Column 8, lines 52-65). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use

Wilson's heat shrink tube during Noone's method in order to most efficiently bond the materials together.

Regarding Claim 5, Noone shows the process as claimed as discussed in the rejection of Claims 1 and 4 above, but he does not show specific melting points. Wilson teaches that the first polymer segment has a melting point that is greater than about 400°F and the second polymer segment has a melting point that is less than about 400°F. Wilson teaches using a blend of PEBA and approximately 30% $BASO_4$ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 7, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the first polymer segment comprises a polyether-ester elastomer (column 9, lines 20-25). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 9, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 10, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at

the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noone, Benjamin, and Wilson, further in view of Zadno-Azizi (US 2004/0015150). Noone teaches the invention of claim 4 as discussed above, but fails to explicitly teach that the second polymer segment has a melting point that is about 350^{O}F. Zadno-Azizi teaches a catheter outer coating (PEBAX) that has a melting point at about 350^{O}F (paragraph 0177). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a material with Zadno-Azizi's specific melting point for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noone and Benjamin, in view of Ashiya et al (5,947,925), as stated in the paper mailed 21 September 2005. Noone teaches the invention of claim 1 as discussed above but fails to explicitly teach that the second polymer segment comprises a acetal resin/polyurethane blend. Ashiya et al., hereafter "Ashiya," teaches the second polymer segment comprises an acetal resin/polyurethane blend (column 6, lines 40-61, polyoxymethylene is an acetal resin). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Ashiya's specific material for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONICA A. HUSON whose telephone number is (571)272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Monica A Huson
Primary Examiner
Art Unit 1791

/Monica A Huson/
Primary Examiner, Art Unit 1791